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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,434	04/13/2001	Mark A. Emalfarb	3123-4006	5903

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MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,434

Applicant(s)

EMALFARB ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
4a) Of the above claim(s) 6-8 and 13-48 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 9-12 and 49 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-49 are pending in the application.

Claims 6-8 and 13-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-5, 9-12 and 49 are under examination.

Specification

In view of the amendments to the specification deleting the hyperlinks, the objection to the specification is withdrawn.

Drawings

The objection to the drawings is withdrawn with the amendments made to the sequences in Figure 12.

Claim Rejections - 35 USC § 101

The rejection is withdrawn in view of the amendments on the claim made on 7/14/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 9-12, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A). To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

The specification does not provide a written description of a method by which the fungal suspension is characterized by low viscosity and production of a transferable reproductive element upon transfection of a library of DNA vectors. "Transferable reproductive element" is defined at page 10, numerous as a spore, propagule, hyphal fragment, protoplast, micropellet, or other fungal element that is (1) readily separated from other

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such elements in the culture medium, and (2) capable of reproducing itself into a monoclonal culture. However, the specific description in the Examples describes that the specific fungi *Chrysosporium* and *Trichoderma* are the only fungi that exhibits the recited phenotype of low viscosity. In fact *A. niger* out of the five embodied fungi produces a high viscosity that results in hyper branching i.e., high or pronounced filamentous formation that would not be suitable for the physical manipulations involved in high-throughput DNA library screening. If applicants already encountered difficulty in determining which fungi strain would have the characteristic phenotype based on only five fungi, how much more with a skilled artisan? Also, the description describes only the transferable element as the spores. It is not apparent how this single transferable element would be predictive of the other transferable reproductive elements, singly or in combinations. More importantly, if these reproductive elements occur simultaneously, its separate or combined determination is not completely described. It is well known that aerial sporulation causes massive cross-contamination during transfer. In addition, morphologically improved strains of parental strains containing heterologous gene expression cassettes are not suitable as general expression hosts since they cannot be used for the

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exclusive expression of other heterologous polypeptides. Even a single factor as pH can affect the reproductive elements. Xu [the reference cited by applicants (Exhibit 1)] recites at page 5, col. 1 that the mechanism by which pellet formation reduces the protease secretion has not yet been elucidated. The specification is replete with generalities. But the exemplification is limited to *Chrysosporium* that exhibits the desired phenotypic characteristics to enable a high-throughput screening of a library. In biotechnological invention one cannot necessarily claim a genus after only describing a single species because there may be unforeseen results obtained from the species other than those specifically described. Applicants seemed not to be in possession of the huge scope of the genus of the numerous and different fungi capable of producing the different numerous transferable elements. Applicants, at the time of filing, are deemed to have not invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). [Incorporating the fungi *Chrysosporium* in the independent e.g., claim 1 would obviate this rejection].

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B). The as-filed specification does not provide support for the expression of a broad protein encoded by the nucleic acid library. The original disclosure and claims disclose expression of heterologous proteins.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Withdrawn Rejections

In view of the amendments to the claims on 7/7/2004 the rejection under 35 USC 112, second paragraph is withdrawn. However, the newly amended claims are rejected under this statute as follows:

Claims 1-5 and 9-12, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as his invention.

The term "low" in claim 1 is a relative term, which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in

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the art would not be reasonably apprised of the scope of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 9-12 and 49 are rejected under the judicially created doctrine of double patenting over claims 1-25 of U. S. Patent No. 6,573,086 ('086 patent) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claimed mutant of *Chrysosporium* strain comprising a nucleic acid sequence encoding a polypeptide of

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interest of the '086 Patent is obvious over the method of the instant application which uses the same fungi to express the polypeptide of interest. The abstract, for example, of the '086 Patent discloses that the Chrysosporium strain is useful in producing a large amount of polypeptide in economical manner.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Withdrawn Rejection:

The rejection of claims 1-5 under 35 U.S.C. 102(e) over Borchert et al (6,518,042) has been withdrawn in view of the amendments to the claims and applicants' arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 9-12 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Emalfarb et al (WO 00/20555)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Emalfarb et al discloses a method of expressing heterologous proteins from a filamentous fungal host having phenotypic characteristics as low-viscosity by transfecting said filamentous fungal with a DNA library as shown in Figs. 6-11

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that encodes the family of Penicillium. See particularly the Examples at page 23, specifically at page 26 up to page 40, line 10. See also page 18, line 6 up to page 19, line 1 as to the phenotypic low-viscosity property of the fungi. Accordingly, the specific process steps of Emalfarb anticipate the broad claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 9-12, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Royer et al (6,060,305) in view of Shuster et al (6,066,493) and Borchert et al (6,518,042).

Royer et al discloses in Example 8, a method of producing heterologous proteins comprising transforming filamentous fungi *Fusarium graminearum* strain ATCC 20334 cultures grown on a medium. C. Conidia are dislodged in sterile water using a

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transfer loop and purified by filtration. Conidial suspensions are concentrated by centrifugation and incubated with culture medium. Resulting hyphae are trapped on a sterile filter and washed. The hyphae are resuspended and digested. Undigested hyphal material is removed from the resulting protoplast suspension by successive filtration and combined with the protoplast solution. After mixing, protoplasts are pelleted. The protoplast suspension are incubated and transformed with enzymes until transformants appeared. Royer does not disclose transfection of the suspension of transferable element with phenotypic characteristic as low-viscosity and transfection of e.g., protoplasts with a library of DNA vectors.

Schuster discloses mutants of fungi which possess improved growth characteristics in fermentation where the morphology gives rise to lower viscosity in the fermenter, in turn leading to easier mixing, better aeration, better growth, and ultimately, enhanced yield of heterologous polypeptide produced by the mutant strain relative to the parent strain. The host cells exhibit about 90% or less of the viscosity level produced by the parent cell under identical fermentation conditions.

Borchert et al discloses a process of making DNA libraries in filamentous fungal cell. Borchert discloses at col. 3, lines 18-40 that transfection of the filamentous fungal cell

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population with DNA library is use to select a polypeptide of interest. The advantage of the process is the direct expression of the polypeptide from a filamentous fungal cell that is useful subsequently to produce the polypeptide in large scale in a filamentous fungal cell. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to transfect a library of DNA in the filamentous fungal reproductive elements of Royer having the low-viscosity as taught by Schuster and Borchert. The advantages in having a low-viscosity medium as taught by Schuster, above and library of DNA as taught by Borchert provide the motivation to one having ordinary skill in the art to make the modification.

In view of the new art above, applicants' arguments in their REMARKS of 7/2/2004 and 2/1/2005 are moot.

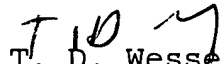
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

September 6, 2005